

BLT SKIN CREAM- benzocaine, lidocaine, tetracaine cream
M2B Pharma LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BLT Skin Cream

DRUG FACTS

Active ingredient

Benzocaine 20%

Purpose

Topical anesthetic

Active ingredient

Lidocaine 4%

Purpose

Topical analgesic

Active ingredient

Tetracaine 1%

Purpose

Topical analgesic

Uses

For temporary relief of pain

Warnings

For external use only

Do not use

- On wounds or damaged, broken or irritated skin
- In large quantities
- At the same time as other topical analgesics or anesthetics
- If you are currently taking medication to control heart rate or rhythm or if you have any type of heart disease
- If you are allergic to PABA, benzocaine, lidocaine, tetracaine or other sulfonamides (sulfa) type drugs
- If you are under the age of 17

When using this product

- Use only as directed. Read and follow all directions and warnings on this label.
- Avoid contact with eyes or mucous membrane
- Do not bandage or cover with any type of clear occlusive dressing
- Do not apply heat (such as heating pad) to area of use

Stop use and ask a doctor if

- If redness or skin irritation is present at application site
- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- You have any heart conditions

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions**Adults and children over 17 years of age:**

- Apply to affected area of pain no more than 3-4 times per day. Do not cover with any occlusive dressing

Do not use on children 17 years and younger without consulting a doctor.**Other Information**

- Store at 20-25 degrees C (68-77 degrees F).
- Store away from heat, sunlight, and excessive heat or humidity

Inactive Ingredients

behentrimonium chloride, caprylic/capric triglyceride, cetearyl alcohol, citric acid, dimethyl isosorbide, ethylhexylglycerin, PEG-150 distearate, phenoxyethanol, polyquaternium-37, water

Questions?

1-877-760-1881

info@bltskincream.com

Principal Display Panel

BLT SKIN CREAM

benzocaine, lidocaine, tetracaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73341-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE	0.01 g in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
POLYQUATERNIUM 37 (200 MPA.S) (UNII: 67C1D6YV24)	
BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73341-001-30	30 g in 1 JAR; Type 0: Not a Combination Product	02/04/2020	
2	NDC:73341-001-01	454 g in 1 JAR; Type 0: Not a Combination Product	12/23/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/04/2020	

